XIII. 510(k) Summary

JUL 11 2002

SUBMITTER: DePuy AcroMed, Inc.
325 Paramount Drive
Raynham, MA 02780

CONTACT PERSON: Lisa A. Gilman

DATE PREPARED: April 18, 2002

CLASSIFICATION NAME: Spinal Intervertebral Body Fixation Orthosis

PROPRIETARY NAME: MONARCH Spine System

PREDICATE DEVICES: ISOLA Spinal System (K993030)
Tri-Fix Spinal Fixation System (K011830)

DESCRIPTION: The MONARCH Spine System consists of pedicle screws, washers, spine plates, spinal rods, slotted connectors, dual rod connectors, J-hooks, polyaxial screws, open hooks, closed hooks, and spherical nuts.

INTENDED USE: The MONARCH Spine System when used with pedicle screws is indicated for degenerative disc disease (defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies). Levels of fixation are for the thoracic, lumbar and sacral spine.

The MONARCH Spine System when used with pedicle screws is indicated for degenerative spodylolisthesis with objective evidence of neurologic impairment, fracture, dislocation, scoliosis, kyphosis, spinal tumor, and failed previous fusion (pseudarthrosis). Levels of fixation are for the thoracic, lumbar and sacral spine.

The MONARCH Spine System is also indicated for pedicle screw fixation for Grade 3 and 4 spondylolisthesis at L5-S1, in skeletally mature patients, utilizing autologous bone graft, having the device fixed or attached to the lumbar or sacral spine and intended to be removed after solid fusion is attained. Levels of attachment for this indication range from L3 to the sacrum.

The MONARCH Spine System when not used with pedicle screws is intended for posterior hook, wire, and/or sacral/iliac screw fixation from T1 to the ilium/sacrum. The non-pedicle screw indications are spondylolisthesis, degenerative disc disease (defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies), deformities (scoliosis, lordosis and kyphosis), tumor, fracture and previous failed fusion.

MATERIALS: Manufactured from ASTM F-136 implant grade titanium alloy or ASTM F-76 commercially pure titanium.

PERFORMANCE DATA: Performance data were submitted to characterize the MONARCH Spine System.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 11 2002

Mr. Frank Maas
Director, Regulatory Affairs
Depuy AcroMed
325 Paramount Drive
Raynham, MA 02767-0350

Re: K021335
Trade Name: MONARCH Spine System
Regulation Number: 21 CFR 888.3050 and 888.3070
Regulation Name: Pedicle Screw Spinal System, and Spinal Interlaminal Fixation Orthosis
Regulatory Class: III, II
Product Code: MNH, MNI, KWP
Dated: April 19, 2002
Received: April 26, 2002

Dear Mr. Maas:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

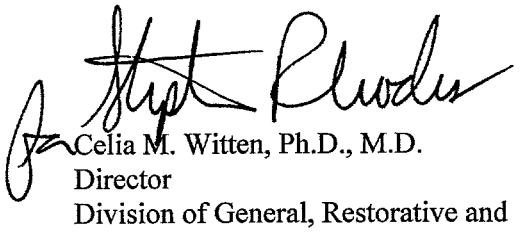
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or at (301) 443-6597, or at its Internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,



Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative and
Neurological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

IV. Indications for Use

510(k) Number (if known): K021335

Device Name: MONARCH Spine System

Indications For Use:

The MONARCH Spine System when used with pedicle screws is indicated for degenerative disc disease (defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies). Levels of fixation are for the thoracic, lumbar and sacral spine.

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(Please do not write below this line - continue on another page if needed)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use: X OR Over-The-Counter Use: _____
(Per 21 CFR 801.109)

(Division Sign-Off)
Division of General, Restorative and Neurological Devices

510(k) Number K021335